February 3, 2009

Health Workforce Pilot Projects Program
Facility-Based Assessment Form
171—07-200
Concord, California

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
Regulation: (Section 92304) Sponsor Information. Sponsor information shall include, but not be limited to the following: (d) Description of funding sources for the project. (f) Composition of Advisory Group (g) An identification of collaborative arrangements with other educational clinical phase. This would include the availability of support services such as library, equipment, etc.	x			Funding source documentation. (FY and amount) Advisory Group and meeting outcomes Contract: Sponsor with participating facility. Sponsor and health care facility relationship. Organizational chart to reflect the working relationship of trainee to supervisor Contract or MOU with a general acute care hospital for emergency protocols, post procedure admissions.	Standardized procedures Needs: 1. Names of nurse practitioners approved to perform the procedure. 2. Reference in standard procedures to the use of medications, e.g. a list.	No report received.	No comments provided.	No comments provided.		Sponsor provided an overview of the project, an executive summary of the status of the project, accompanied with a powerpoint layout describing the project history.
Regulation: (Section 92312) Modifications. Any modifications or additions to approved project: (a) Change in scope of project (b) Change in selection criteria for: trainees, supervisors or employment/utilization sites, project staff or instructors, Curriculum, other. (c) Change in project staff or instructors	x		x x x		Requesting an extension of the project.					New hire; Amy Levi to oversee case competency for the program. The didactic portion of the curriculum is being developed for on-line (web-based) for distance learning.

Health Workforce Pilot Projects Program
Facility-Based Assessment Form
171—07-200
Concord, California

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
Regulation: (92305), (92311). Trainee Information. Plan to inform trainees of their responsibilities and limitations under the Health Workforce Pilot Project statutes and regulations. (a) Name, work address and telephone number of the trainee. (b) Name, work address of the supervisor. and telephone number and license number	x			Training agreement. Public Disclosure document regarding availability of trainee information. Listing of trainees and supervisors per participation site - license Information.					Recommendations: 1. All NP/APCs should sign Standardized Procedures on 1 page as recommended by the BRN. 2. To protect the security of women, I recommend that home addresses be removed from the licensing web sites, which allow public access to personal information such as home addresses.	Training Agreements on file. OSHPD has agreed, with the sponsor, to certain confidentiality protocols for this site visit. The Clinic and Sponsor are concerned about participant confidentiality. Thus, the site will have a HIPPA agreement form for you to review and sign. Note also that we will (1) refer to the trainees and preceptor by their codified numbers, (2) review the patient records abstraction summaries, the patient satisfaction abstraction summaries and other clinical protocols here on site. The sponsor has asked that, as part of the confidentiality agreement, we not remove these documents from the site.

Health Workforce Pilot Projects Program
Facility-Based Assessment Form
171—07-200
Concord, California

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
Regulation: (92306). Curriculum. (a) A description of the minimum level of competence the trainee shall achieve before entering the employment/utilization phase of the project. (b) A description of the content required to meet this minimal competency. (c) A description of the methodology utilized in the didactic and clinical phases. (d) A description of the evaluation process used to determine when trainees have achieved the minimum level of competence. (e) An identification in hours and months of the time required to complete the didactic and clinical phases.	x x			Curriculum Availability. Descriptions of: Observed Performance Assessment. Procedure Log Patient complications tracking. trainee clinical schedule.					This visit was focused on interviews of Advanced Practice Clinician (APC)/Trainees, Preceptor, Clinical Administrators and members of the Research Team. Due to very strict confidentiality protocols, clinical documentation was reviewed on site and not removed from the site. Curriculum was described as being self-paced and appropriate for each trainee. Didactic curriculum is 30 hours and each APC must pass a written examination before progressing to the hands-on clinical training module.	A copy of the curriculum was available. The Research Coordinator provided The Team with abstraction summaries of patient logs and patient satisfaction surveys-follow-up information. Trainee hours/ scheduled will be obtained via interviews with the trainee and preceptor. The Trainees are to complete a minimum of forty aspiration procedures under direct supervision of the preceptor and a minimum of sixty procedures with the preceptor in residence but not in direct-presence supervision. The Preceptors find that there is flexibility in the number of procedures as enunciated above. The preceptors and

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
										trainees, on occasion, may find a need to increase the level of competency-number of procedures at each stage.
Regulation: (92101) Minimum Standards. Each Pilot project shall: (a) Provide for patient safety. (b) Provide qualified instructors to prepare trainees. (e) Demonstrate that the project has sufficient staff to monitor trainee performance and to monitor trainee supervision during the employment/utilization phase. (g) Demonstrate the feasibility of achieving the project objectives.	x			Clinical protocols including management of emergencies related to callbacks, general acute hospital care admissions and post care. Listing of trainees and Supervisors per participation site - license Information.	All trainees are trained by T-11					*Standardized Procedures:* The Sponsor and medical director for the Concord facility was asked to include the following in the standardized procedure for the project: (1) names of the trainees approved for the performance of the project's procedures; and (2) reference the approved medications that may be administered by the trainee under this project.
Regulation: (92308) Monitoring (a) A description of the provisions for protecting patients' safety. (b) A description of the methodology used by the project director and project staff to provide at	x x			Review: Chart and quality management reviews Observed performance assessment	Reviewed four charts. Need to define what "none" and "other" means in reference to the					*Recordkeeping:* The trainees and preceptor keep a log of the procedures per each trainee. Trainees/preceptors

Health Workforce Pilot Projects Program
Facility-Based Assessment Form
171—07-200
Concord, California

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
least quarterly monitoring of the following: (1) Trainee competency. (2) Supervisor fulfillment of role and responsibilities (3) Employment/utilization site compliance with selection criteria.	 x x			Procedure Log Patient complications tracking trainee clinical schedule Skills and experience inventory assessment forms. Clinical Satisfaction - Staff surveys. (quarterly review)	type of insurance.					have follow-up calls to the consented patients as a post protocol for quality of care and continuity of care. Complication incidents by provider type: APC = 8 MD = 3 TOTAL = 11
Regulation: 92309. Informed Consent. The plan used to obtain prior informed consent from patients to be treated by trainees or those legally able to give informed consent for the patients shall be described. It shall include, but not be limited to the following: (a) A description of the content of the informed consent. (1) Explanation of the role and status of the trainee, including the ready availability of the trainee's supervisor for consultation. (2) Assurance that the patient can refuse care from a trainee without penalty for such a request. (3) Identification that consenting to treatment by a trainee does not constitute assumption of risk by the patient. (b) Provision that the content of the informed	 x			Informed consent form- signed by patient or patient representative.	Informed consent obtained by the project coordinator, which was without any major concerns.					*The Research Coordinator* is the individual responsible for the Concord facility's record keeping and data entries for the APC project. The Research Coordinator obtains the informed consent from perspective patients. She has a protocol which establishes the method for obtaining the consent, notifying the trainee and preceptor of patient availability. The Research Coordinator will also assist in obtaining post

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
consent, either written or oral, shall be provided in a language in which the patient is fluent. (c) Documentation in the patient record that informed consent has been obtained prior to providing care to the patient. (d) Provision for obtaining witnesses to informed consent. Written informed consent must be witnessed. Oral informed consent obtained by the trainee shall have a third party document in writing that he/she has witnessed the oral consent. (e) Informed consent need be obtained only for those tasks, services, or functions to be provided as a pilot project trainee.										procedure follow-up telephone surveys. She is also responsible for data entry and submission of data for that site to UCSF.
Regulation: (92310) Costs. A plan for determining estimated or projected costs shall include, but not be limited to the following: (a) An identification of the average cost of preparing a trainee. This shall include cost information related to instruction, instructional materials and equipment, space for conducting didactic and clinical phases, and other pertinent costs. (b) An identification of the average cost per patient visit for similar care rendered by a current provider of care. (c) An identification of predicted average cost per patient visit for the care rendered by a trainee.				Budget Updates. Proforma's Cost of training: administrative, didactic and clinical phases.	The project will be collecting data around the cost of a clinicians doing a procedure vs. a medical doctor (M.D.) Not discussed at this time, but in the process.					Updated cost data not available. The principal Investigator indicated that she is in the process of looking at costs data.

Health Workforce Pilot Projects Program
Facility-Based Assessment Form
171—07-200
Concord, California

Elements of Implementation	Regulation Compliance			Factors Considered	Assessment Remarks					
	Met	Not Met	N/A		BRN	MBC	Assoc. of Reproductive Health Professionals	American College of OB-GYN, District IX	Technical Consultant UCD FNP/PA Program	OSHPD-HWPP
Regulation: 92603. Site Visits. Site visits shall include at least the following: (a) Determination that adequate patient safeguards are being utilized. (b) Validation that the project is complying with the approved or amended application. (c) Interviews with project participants and recipients of care (d) An interdisciplinary team composed of representatives of the healing arts boards, professional organizations, and other State regulatory bodies shall be invited to participate in a site visit.	 x x x x			Observed performance assessment. Procedure Log. Patient complications tracking Trainee clinical schedule. project safety committee report	3 interviews were conducted. All three were post-training clinicians.					The site evaluation team was provided with abstraction summaries of patient data and patient satisfaction survey data. The team also interviewed three trainees and one preceptor. Total procedures: 561 529 patients completed the patient satisfaction survey.